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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,482	12/21/2001	Janet A. Warrington	3445	2372

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EXAMINER	
SMITH, CAROLYN L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/028,482	WARRINGTON ET AL.	
	Examiner	Art Unit	
	Carolyn L Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,17 and 20-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,17 and 20-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Applicant's amendments and arguments, filed 1/18/05, with respect to the claim 1 objection and the NEW MATTER rejection(s) of claim(s) 15, 16, and 22 have been fully considered and are persuasive. Therefore, the objection and rejections have been withdrawn. However, upon further consideration, new ground(s) of rejection are made in view of current claim amendments to claim 1.

Claims herein under examination are 1-4, 17, and 20-27.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 17, and 20-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 6, recites the phrase "3 to 15 kilobases" which is vague and indefinite. It is unclear if this range is supposed to include 3-15000 bases or 3000-15000 bases. Clarification of this issue via clearer claim wording is requested. Claims 2-4, 17, and 20-27 are also rejected due to their dependency from claim 1.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 17, 20, and 26 are rejected under 35 U.S.C. 102(a) and 35 U.S.C. 102(e)(1) as being anticipated by Bass et al. (2001/0039014 A1).

Bass et al. disclose amplifying large nucleic acids by PCR in which amplicons of up to 40 kb are generated (paragraph 0235) which encompasses amplicons of 3 to 15 kilobases, as stated in instant claim 1. Bass et al. disclose automated devices and systems for arraying nucleic acids and for making and copying arrays, for performing in vitro translation and/or transcription of nucleic acid libraries, and for screening (abstract and paragraph 0002). Bass et al. disclose automated systems to assess biological phenomena including gene expression levels in response to stimuli (high throughput DNA genotyping), as well as integrated systems for performing mixing experiments (sample preparation method), DNA amplification (PCR), and DNA sequencing (genotyping) (paragraph 0003). Figure 13 shows a DNA fragment preparation device (paragraph 0111). Bass et al. disclose nucleic acid fragments are optionally contacted in a

single pool or in multiple pools (paragraphs 0018 and 0058) which represents pooling aliquots of a plurality of amplicons into a plurality of pooled samples, as stated in instant claim 1. Bass et al. disclose laboratory attempts to meet increased demand for product development and research with minimal use of laboratory personnel (paragraph 0003). Bass et al. disclose using a nucleic acid shuffling module to dispense elongated nucleic acids into one or more multiwell plates (paragraph 0019) which represents an automated high density probe array loader, as stated in instant claim 1. Bass et al. disclose automated systems with robotics and fluid handling modules such as for microtiter tray manipulation (paragraph 0006) which is reasonably interpreted to be a sample preparation automation system, as stated in instant claims 1 and 2. Bass et al. disclose samples can be treated with at least one disruptive physical condition, such as freeze-thawing, cold-hot cycling (paragraph 0573) which represents the presence of a refrigerated unit, as stated in instant claim 1. Bass et al. disclose using a microamplifier in which DNA is placed in a microcapillary and moved through three resistors whose temperatures are programmed (paragraph 0550). Bass et al. disclose using a robotic arm to move the capillary (paragraph 0550). As these modules are part of an integrated system (Figures 1A to 7), the temperate treatment and robotic arm microamplifier are connected with the nucleic acid shuffling module representing the probe array loader, as stated in instant claim 1. Bass et al. disclose using devices and systems using an array of reaction mixtures that include one or more diversified nucleic acids (i.e. mutagenized or transcribed mutagenized) (paragraph 0010) which represent variation detection (an automated high density probe array loader), as stated in instant claim 1. Bass et al. disclose libraries that involve hybridization to a selected nucleic acid probe (paragraph 0195). Bass et al. disclose using PCR with techniques for rapid genotyping and

quantification with hybridization probes (paragraph 0332). Since the probes are for the one or more diversified nucleic acids as described above, these probes represent "about 400,000 different sequence probes", as stated in instant claim 1. Bass et al. disclose a physical array with a set of specified elements (features) arranged in a specified spatial arrangement and a logical array with a set of specified elements that permits access to the elements of the set (paragraph 0133). As it is well known that there are many features in an array where probes are placed, it is reasonably interpreted that each probe is present in a different feature of the array, as broadly stated in instant claim 1. Bass et al. disclose using two probes labeled with different fluorophores that transfer energy between them to become excited and detected if a desired genotype is present (paragraphs 0335 and 0336) which also represent "about 400,000 different sequence probes", as stated in instant claim 1. Bass et al. disclose the devices and integrated systems contain a bar-code sample tracking module which includes a bar code reader and a computer readable database (memory) with bar codes for corresponding arrays (paragraph 0011), as stated in instant claims 1, 3, 17, and 26. Bass et al. disclose data obtained by the detection device is processed, stored, and analyzed by a computer system including a microprocessor and memory (paragraph 0423). Bass et al. disclose using PCR to amplify elongated nucleic acids to produce an amplified array of elongated nucleic acids (paragraph 0019) which represents long range PCR amplification, as stated in instant claim 1. Bass et al. disclose various sources of nucleic acids, including cDNA, DNA generated by reverse transcription, and antisense nucleic acid (paragraph 0020), as stated in instant claim 20. Bass et al. disclose simultaneous addition, cleaving and synthesizing of one or more DNA and antisense nucleic acid (paragraphs 0019 and 0070). Bass et al. disclose using nucleic acid fragments up to about 100 bases (paragraph 0238).

Bass et al. disclose a nucleic acid shuffling or mutagenesis module which is preceded by a module which allows overlapping of oligonucleotides to be assembled into multimers (paragraph 0014), which represents tiling. Bass et al. disclose selecting, recombining, and re-arraying one or more members (nucleic acid) of an array (paragraph 0082) which represents a contiguous sequence being tiled on an array. Bass et al. disclose the analysis device allows one to quantitatively measure the frequency of recombination between DNA polymorphisms in parental genes (paragraph 0554). Bass et al. disclose the use of molecular beacons which are probes that can be used in various amplification reactions that report the presence of specific nucleic acids (region of interest), including the detection of single-nucleotide variations (paragraph 0329) which represents determining the genotype of a plurality of single nucleotide polymorphisms in a region of interest, as stated in instant claims 1 and 4.

Thus, Bass et al. anticipate the limitations in claims 1-4, 17, 20, and 26.

Applicants have amended in subject matter from cancelled claims 18 and 19 into claim 1. It is noted that the subject matter of claim 18 was already addressed in the previous FINAL rejection. Upon further consideration of the prior art, it is noted that amplicons of 3 to 15 kilobases are anticipated by Bass et al.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

February 2, 2005

Ardin H. Marschel 2/5/05
ARDIN H. MARSCHEL
PRIMARY EXAMINER